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EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	PAPER NUMBER
1792	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/747,996	CHEN ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8-20,34-36,38 and 40-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42/40, 43-45 and 46/47, 48* is/are allowed.

6)☒ Claim(s) *2-6,8-17,34-36 and 38* is/are rejected.

7)☒ Claim(s) *18-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080828*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Objections

Claims 40 and 42 are objected to because of the following informalities:

In claim 40, the claim dependency needs clarification.

In claim 42, lines 6 AND 7, "the length" should be changed to --a length--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, Applicants recite the pressure apparatus and it is unclear how this claim further structurally limits the system of claim 17 which has a pressurizing device. Clarification is necessary.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17/2-4, 10-16, 34-36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033) and Heller et al (US 2003/0215564).

XP provides a system for coating an implantable medical device comprising a coating composition in a cup (E), the excess composition in a bottom of the cup defining a reservoir of

the coating composition (E), the composition being a polymer and therapeutic agent, the cup including a hollowed tubular textile/cloth/fiber//filament type liner body; an applicator including a planar or flat sheet (C, D) including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface via wicking/capillary action; and a rotatable support element or mandrel (A) to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator wherein the cloth liner body is configured such that when the mandrel supported medical device is inserted into the bore by user hands and rotated against the inner surface of the liner body, coating composition is applied to the medical device (see embodiments, of Figs. 1 and 2). XP is silent concerning 1) a temperature controller in communication with parts of the system (at least one of applicator, support element and reservoir) so as to control the temperature (heating or cooling) of the coating material and 2) a pressurizing device in communication with the applicator or reservoir for conveying coating composition from the reservoir to the coating surface. However, it was known in the art, at the time the invention was made, to provide a temperature controller (enabling heating or cooling) in communication with of a stent manufacturing/processing chamber in order to maintain a desired temperature of the coating on stent in order to prevent degradation of the coated stent product as evidenced by Hijlkema et al (col. 3, lines 11-24; col. 5, lines 9-24; col.6, lines 31-44 and lines 60+ to col. 7, line 12). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Hijlkema et al in communication with at least the XP reservoir in order to maintain a desired temperature of the coating on stent to prevent degradation of the stent product. In addition, it

was known in the art at the time the invention was made to provide a manipulative type mandrel device for effecting vertical motion of the mandrel, rotary motion of the mandrel, and/or vibratory motion of the mandrel to facilitate coating of a stent mounted on the mandrel as evidenced by Heller [0026]. One of ordinary skill in the art would readily appreciate the use of a manipulative type mandrel device as taught by Heller in the system as defined by the combination above, in order to allow for automated manipulation of the mandrel with the stent thereon which would in turn allow for pressurizing of the XP system to allow for transfer or conveyance of coating composition to the stent product.

With respect to claim 2, the applicator when placed in the cup is deemed a hollow tubular body having a bore for receiving the medical device.

With respect to claim 3, there is no teaching of a half tubular body configured to receive the device; however, it would have been within the level of one skilled in the art to make the applicator of half of a tubular body so as to use less material to make the coating system and thereby lower manufacturing costs.

With respect to claim 4, see coating surface (C) which is flat as shown in Fig. 1 of XP.

With respect to claim 10, the system as defined by the combination above would allow for rotation of the medical device via use of the manipulative type mandrel device.

With respect to claims 11 and 13, the implantable device/stent, has been given no patentable weight.

With respect to claim 12, the system as defined by the combination above provides for a linearly movable applicator because the liner is insertable and thus removable by hand from the cup.

With respect to claim 14, the system as defined by the combination above would provide for pressure to be applied to composition in the reservoir via use of the manipulative type mandrel device.

With respect to claim 15, the applicator can be made from sponge which can be natural or synthetic to include a polymer.

With respect to claim 16, the type of material used to make the applicator suitable to provide for coating of the medical device is deemed to be within the purview of one skilled in the art.

With respect to claims 34-36, the characteristics of the applicator from including uniform pores to the applicator having capillaries go to the characteristics of the foam or cloth. Such characteristics of the applicator would be well within the purview of one skilled in the art so as to control the amount of coating material to be applied and retained on the medical implant device.

Claims 5, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033) Heller et al (US 2003/0215564) as applied to claim 17 above, and further in view of Sarada et al (US 5,136,968).

The teachings of XP, Hijlkema, and Heller have been mentioned above and while a planar sheet is used to coat the stent including foam, cloth (fibre/filament based material), etc., XP/Hijlkema/Heller fail to suggest the pore characteristic (pore radius of. 1 microns to 1000 microns) of the foam or cloth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to facilitate metering of coating material from the coating reservoir as evidenced by

Sarada (col. 3, lines 12-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the system as defined by the combination above with a porous region having a pore size including a radius in the claimed range in order to allow for metering of the coating material from the reservoir. Furthermore, it would have been obvious to one of ordinary skill in the art to determine, via routine, experimentation, the appropriate pore characteristics including pore radius and degree of porosity, in accordance with the medical device being produced and the amount of coating material sought to be retained on the medical implant device.

With respect to claims 8 and 9, the XP system provides for a foam or sponge based porous sheet but a layered sponge or foamed sheet having different porosities, is not set forth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to provide for metering of coating material from the coating reservoir adjacent another porous applicator with the latter porous applicator having a greater pore dimension as evidenced by Sarada (col. 3, lines 5-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the system as defined by the combination above with two porous regions having different pore dimensions in order to provide a layered sponge or foamed sheet in order to control the wicking of the coating from the reservoir to the sheet to the medical device so as to provide a desired thickness of coating thereon.

Allowable Subject Matter

Claims 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 42/40, 43, 44, and 45 would be allowable.

Claims 46/47, 48 would be allowable.

Claims 46-48 would be allowable because there is no teaching or suggestion in the prior art of a system for coating an implantable medical device with a coating composition, comprising the combination of a reservoir holding a coating composition; an applicator including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface; a support element to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator; and a pressure apparatus configured to supply a gas to, and being in fluid communication with the coating composition so as to enhance the loading of the coating surface.

Response to Arguments

Applicants' arguments filed 8/28/08 have been fully considered but they are not persuasive.

Applicants contend that any obviousness rejection including the teachings of Hijlkema should be withdrawn as being improper because Applicants' system is configured to coat a

prosthesis using a temperature controller while Hijlkema modifies the surface temperature of a work piece to make the coating more resistant to chipping or cracking by making the surface more cold or hot. It appears that the Office has concluded that the standard for obviousness may be met by a mere showing that all elements in the claim were separately known and capable of being combined to re-create the invention. Thus, one of ordinary skill would have been motivated to use a temperature controller in any part of a stent manufacturing system apparatus in view of the teaching in Hijlkema.

Applicants' argument with respect to Hijlkema is well taken in that Applicants' claimed invention has been deemed obvious because Applicants have combined known structural features used in apparatus for processing stents, thus it would be improper to grant patentability of the instantly claimed invention. In view of the primary reference, XP, it would have been common sense to provide for temperature control of the system because in some instances the coating material may be viscous, wherein temperature control would allow for control of the viscosity of the material being applied to the stent. Hijlkema alludes to temperature control about the processing of a coated stent to minimize degradation of the stent product as noted in the citation above. To provide for a temperature controller in the XP system would be well within the purview of one skilled in the art.

Applicants argue that any obviousness rejection including the teachings of Heller should be withdrawn as being improper because Heller does not teach a pressurizing device as instantly claimed. Heller describes a process by which a stent is spun and/or vibrated when it is being sprayed by a coating. Not only is Heller referring to a different type of coating system, i.e., one that uses a spray, the reference is totally devoid of a pressurizing device in communication with

the applicator or the reservoir for enhancing the conveyance of the coating composition from the reservoir to the coating surface.

This argument is also well taken in that Heller does not explicitly teach a pressurizing device. Heller teaches a manipulative type mandrel device for effecting vertical motion of the mandrel, rotary motion of the mandrel, and/or vibratory motion of the mandrel to facilitate coating of a stent mounted on the mandrel. The primary reference, XP, provides for manipulation too of the stent on a mandrel but does not show the structure or means to effect the rotation of the stent. Presumably, a user could manipulate the mandrel by hand OR means could be used to manipulate the mandrel automatically so a user would not be needed to result in a automated system. In light the manipulative mandrel device of Heller which is used for coating stents, one of ordinary skill in the art would readily appreciate use of such a manipulative mandrel device in the XP system to provide for automated manipulation of the stent during coating to do away with archaic manual manipulation. The vibratory motion as well as the vertical motion would effectively pressurize the system to cause more coating to be applied to the stent when placed on the manipulative mandrel device within the coating cup.

Thus, the cumulative addition of a temperature controller and an automated mandrel manipulator to the XP stent coating system would be within the purview of one skilled in the art and thus the obviousness rejection combining the teachings of XP with Hijklkema and Heller stands.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

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December 23, 2008